# Health Information Technology Standards Committee
# Final
# Summary of the February 16, 2011, Meeting

## KEY TOPICS

### 1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants this meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available online. She conducted roll call, and turned the meeting over to HITSC Chair Jonathan Perlin.

### 2. Opening Remarks and Review of the Agenda

Perlin thanked Committee members who attended the President's Council of Advisors on Science and Technology (PCAST) Report Workgroup hearings, which had just concluded. He then reviewed the afternoon's agenda.

In his opening comments, HITSC Co-Chair John Halamka said that as they look at the ecosystem of the HIT Policy Committee (HITPC), the Standards Committee, and the Standards and Interoperability (S&I) Framework, the question that arises is how all of these entities intersect and what is the role of this Committee.

During this meeting, Committee members were given the opportunity to articulate any concerns about the S&I Framework. How can they assure a successful, whole process from Policy Committee to Standards Committee to S&I Framework to finished process? Recognizing that a notice of proposed rulemaking (NPRM) will be issued soon for meaningful use Stage 2, it is important to know what must be done and by when, in order to contribute to that effort. Next month, the HITPC will finalize recommendations about meaningful use Stage 2 components. The HITSC then must quickly consider what needs to be included in the S&I Framework. They need to agree on how they can work together with the S&I Framework, and organize themselves to work within the necessary timeframe.

### 3. Privacy and Security Standards Workgroup Update

Halamka introduced this update by posing the question of whether the Workgroup should be looking at specific instructions for implementation guidance, or whether it should simply define all of the characteristics of a certificate and then work with S&I Framework to develop the process.

Privacy and Security Standards Workgroup Chair Dixie Baker announced that Mike Davis, a Senior Security Architect from the Veterans Health Administration (VHA), has joined the Workgroup. The group has been given an assignment to work on digital certificates to authenticate organizations, and also provider directories. They have started on the digital

certificates, and has held two meetings to explore the standards available for authenticating organizations and software. Workgroup members also heard presentations from ONC's Arien Malec on how digital certificates were used in the Nationwide Health Information Network (NHIN) Direct Project, and from Rich Kernan on the NHIN Exchange specifications, known as NHIN Connect. Both explained how digital certificates are used to authenticate organizations.

Mike Davis talked to the Workgroup about digital certificates in VHA to authenticate individuals. This was an increased level of detail compared with authenticating organizations, but the basic technology and standards are quite similar. Then, the Workgroup discussed forging a complementary relationship between the S&I Framework and the HITSC.

Workgroup Co-Chair Walter Suarez noted that in addition to provider directories, the Workgroup is examining entity-level directories, which have already been reviewed by the HITPC. Soon, both sets of directory recommendations will be presented to the HITSC.

*Discussion*

- In response to a question by John Halamka, Suarez said he anticipates that a priority of the S&I Framework will be to survey all provider directory activities by the state, regional, and private organizations. His expectation is that the Privacy & Security Standards Workgroup will provide the guidance and evaluative criteria for the S&I Framework to conduct in-depth analyses on the approaches and existing standards, and then return to this committee with recommendations.

- Carol Diamond pointed out that this topic is also under discussion in the Privacy & Security Tiger Team on authentication. She suggested that all of these activities should be kept in close coordination.

**4. Quality Measures Workgroup Update**

Halamka noted that there will be increasing numbers of quality measures with meaningful use Stages 2 and 3. Thomas Tsang, Medical Director for Meaningful Use and Quality at the ONC, updated the group on some of the work that has been carried out regarding quality measures on the policy side, and discussed the vocabulary set and standards that they are hoping for from this group. He shared slides with the group providing background on the topic, as follows:

- Stage 1 Meaningful Use requires 3 core and 3 additional clinical quality measures (CQMs) for eligible professionals (EPs) and 15 CQMs for hospitals to be reported (aggregate level data for numerator, denominator and exclusions through attestation).

- Stage 1 contains 44 ambulatory care measures for EPs.

- Stage 2 incorporates a transparent and collaborative process for prioritization of the measure concept/selection process.

- The HITPC Quality Workgroup has created six tiger teams focused on these activities.

Tsang acknowledged that the Stage 1 measures were retooled with electronic specifications, which he said was not the best process, retrospectively. Many of these measures cannot simply be mapped out from paper-based to electronic. They hoped to leverage the information and resources available in an electronic health record (EHR) to produce new measures that would be meaningful and parsimonious. The 44 measures in Stage 1 are very specialty-focused and disease-focused. The ONC desires cross-cutting measures that can take advantage of the longitudinal nature of EHRs.

Tsang presented an illustration of the Quality Measures Workgroup's workflow. The ONC received more than 1,100 comments and measure suggestions during a public comment period for Stages 2 and 3. Some are at different levels of development, with most needing to be developed over the next 2 years. The Office is trying to secure funding for the development process—this is the point at which linkage needs to be made between the HITSC and HITPC.

The HITPC has developed a series of suggestions for measures and measure concepts. The ONC is asking the HITSC to offer guidance on the structured data elements.

A diverse set of subject matter experts and federal *ex-officio* members from various agencies serve on the Quality Measures Workgroup, which is chaired by David Blumenthal and co-chaired by David Lansky. The Workgroup has identified five measures priority domains: (1) patient and family engagement, (2) clinical appropriateness, (3) care coordination, (4) patient safety, and (5) population and public health. The criteria being used to consider domains and measures include:

- State of readiness – state of measure development and pipeline/endorsement status.
- HIT-sensitive – evidence that measure can be built into EHR systems.
- Parsimony – applicable across multiple types of providers, care settings and conditions.
- Preventable burden – evidence that measurement can support potential improvements in population health and reduce burden of illness.
- Health risk status and outcomes measurement – supports assessment of patient health risks that can be used for risk adjusting other measures and assessing change in outcomes.
- Longitudinal measurement – enables assessment of a longitudinal, condition-specific, patient-focused episode of care.

A superset of measure concepts and measures will be recommended; individual tiger teams will meet for final recommendations; and further Workgroup attention will be given to capturing patient-reported measures, integrating multiple, longitudinal data sources, and considering a framework for quality measures reporting.

Next, Tsang showed a slide from the National Quality Forum (NQF) on Quality Data Set (QDS) elements illustrating an information model that can serve as a foundation of data elements cross-

walked to certain vocabulary sets that can standardize thinking in measure development and interoperability. He listed the following issues for HITSC consideration: (1) recommendations and feedback on data elements for future e-measures (using the QDS model developed by NQF, funded by HHS); (2) guidance and recommendations needed on the evolution of QDS; (3) guidance on vocabulary sets for e-measures; and (4) recommendations on methodologic issues related to eQMs (e.g.-patient self reported measures, delta measures).

*Discussion*

- Halamka noted that these efforts may impose a tremendous overhead burden in the data capture and programming required for exclusionary criteria that may enhance the face validity of the data and questioned the costs and benefits. What is the cost of every exclusionary criteria that they add? Tsang suggested that it be made explicit that if a measure is too onerous to include, a provider can take the hit on their score and leave it out.

- Janet Corrigan pointed out that these measures were not intended for EHRs. However, there is a school of thought that face validity is very important. The measures must take into account the things that people who are on the front lines and collecting this information think are important. They keep hearing from their expert panels, which are composed primarily of health care providers, that it is important to have a long list of exclusions. She added that in the measurement world right now, there are two kinds of measures: (1) those developed to run off the paper records and take everything into account that might be potentially necessary, and (2) those that run off of administrative and claims data. Consequently, what they have measures for are polar opposites. For EHRs they are trying to strike a middle ground.

- Halamka noted that certain aspects of workflow now need to be changed in order to capture the necessary data. An odd side effect is that although certain functional criteria were not intended to be included in Stage 1, they were actually necessary in order to handle the new measurements accurately.

- David McCallie explained that this is quite burdensome to the software process. As they contemplate new measures, the lead time necessary for the software is profound for many reasons—not the least of which is workflow—both in the software development and in the institution. All of the major questions his clients have relate to quality measures. If a significant amount of new quality measures are added late in the process, vendors and clients will not have time to adjust accordingly.

- McCallie also noted that longitudinal records require some form of health information exchange (HIE). The status of HIE for Stage 2 appears somewhat confused and uncertain, so it may not be appropriate to suggest that many longitudinal measures make sense if it is not clear what is happening with HIE.

- Carol Diamond asked whether it has been decided that the Centers for Medicare and Medicaid Services (CMS) will be collecting detailed, identified data on patients given that there appears to be an intention to add additional data sets and standards to the summary

quality measures being reported. Tsang said that this has not been decided as a policy, and at this point the CMS is not collecting individual patient data. Halamka said that the Quality Reporting Document Architecture (QRDA) does assume the possibility of collecting patient-specific, patient-identified data.

- Janet Corrigan noted that it will be important to connect measure developers with a test bed of organizations that have EHRs running, because the established measure developers are used to the paper-based environment. It also will be critical to provide some clear direction to the developers up front on what is needed in terms of exclusions, etc. She cautioned that they will get very different measures if multiple measure developers are used because they use different tools. It would be beneficial to structure some of these processes.

- Karen Trudeau commented that the Department of Defense has been wrestling with how to document various items related to radiology procedures. Particularly with wounded warriors who may have had 20 or 30 surgeries, measuring cumulative radiology levels is a critical question, but they do not know how to measure it. There are 6 months remaining to develop Stage 2 criteria and there may be a need to create tightly coupled workflow procedures to make such a measure a reality.

- Tom Tsang said that over the next 2-3 weeks, there will be a final list of measure suggestions and concepts. He proposed that the HITSC Quality Workgroup review this list (which will be recommended by the HITPC Quality Workgroup) to determine whether it makes sense or if some of the proposed measures are too aspirational. Karen Trudeau commented that it would be advantageous to include aspirational items on the list, because these are exactly the issues that the S&I Framework must address. Given that the standards must be developed 12-18 months before they can be provided to implementers, this is work that needs to be done in preparation for Stage 3. She appreciates this list as a useful way to prioritize future work.

- It was noted that the HITSC will replace Janet Corrigan as Chair of the HITSC Quality Workgroup, as she feels that she has a conflict. Anyone interested Committee member was asked to contact Judy Sparrow for consideration.

- John Derr reminded the group that a statement was made a number of months ago about including other providers in Stage 2 quality measurements. Even though these other providers are not eligible for incentives, they still need to be included in the Stage 2 quality measurement exercise, and he does not see this recognized as of yet. He noted that there is not a good answer for those in the long-term care community as to why they are not being included; he also commented that even in the PCAST Report, long-term care was mentioned only once. Halamka emphasized that it is critical to include every element of care, and it is important to include these stakeholders. Jim Walker agreed, noting that in Stages 2 and 3, there are discussions about transitions of care, and these other stakeholders must be included.

- Dixie Baker noted that the ONC is concerned about the low EHR adoption rate among underserved populations. Recently, she became aware of the additional burden that these quality measures are placing on providers who care for the underserved, and who are funded

by multiple federal agencies. Her concerns are that measures may not easily be applied to that segment of the population, and that these are additional reporting requirements over and above what are already in place. She asked if "preventable burden" should also apply to the burden on software developers and providers. She suggested that providers from some of these organizations be included in the Workgroup. Tom Tsang pointed to the harmonization efforts currently underway with the Affordable Care Act, which should help to ease the reporting burden of providers to the underserved.

- Judy Murphy noted that Stage 1 quality measures seem isolated, and expressed enthusiasm that Stage 2 is being organized around a framework. That said, there is a relationship between this framework and the current meaningful use criteria. She suggested that perhaps the quality measures should be married in a tighter way to meaningful use criteria, rather than being separate.

- Jonathan Perlin noted that measures that support the interactivity of different providers and the patient and the process of care become more robust with longitudinal data. In considering the potential differences between accountability and informational measures, the former are specific in that they are the interrogative of implied decision support. That becomes important in that they are building standards to support the implementation of decision support.

- Halamka emphasized that a new Quality Workgroup Chair must be selected, a QDS tutorial should be developed, and Quality Workgroup membership overall should be enhanced.

**5. Clinical Operations Workgroup Update**

Halamka indicated that the HITSC has received a transmission letter from the HITPC regarding patient matching. This is not work that has been assigned, and it requires building code sets around demographics to create the most robust patient matching. Because this is about code sets and vocabularies around demographics, his assumption is that these tasks will fall to either the Clinical Operations or the Vocabulary Workgroup.

Clinical Operations Workgroup member Liz Johnson offered a brief update on a hearing being planned for March 28 about identifying barriers and enablers for device interoperability. Panels for the hearing will include stakeholders representing a variety of device interoperability perspectives and will be organized around the following areas: (1) patients/consumers, (2) providers, (3) interoperability and data integration, (4) data accuracy and integrity, (5) device and data security, and (6) universal device identifier. Findings from this hearing will be presented at the April HITSC meeting.

*Discussion*

- Nancy Orvis pointed out that the Workgroup's March hearing should be broadcast to the long-term care, chronic care, and home care communities. Part of the reason this industry is coming forward is to create seamless data flow. She wants to make sure they explicitly make that link. She also suggested that medical device product information as well as the data it

transmits be included in the hearing. One of the key issues in an EHR that has not been resolved is a patient care summary of medical care devices necessary to maintain a person's health. It is important to note that durable medical equipment, artificial limbs, etc. are considered medical devices.

- Carol Diamond offered to assist with development of the hearing, particularly the patient/consumer panel. She also noted that more than 100,000 people have downloaded their medical records, from the VA for example. It would be helpful to gain a better understanding of the simple and more complicated interactions in which consumers are engaged.

- In response to a question from Cris Ross, Johnson said that the Workgroup does not have a formal definition of the term "device," but Workgroup members have discussed the FDA definition and will provide that to the Committee prior to the March hearing. Ross suggested that they include in their definition devices for diagnostics as well as ongoing care. He was not suggesting devices for all treatments, but home-health devices such as glucometers, pulse oximeters, and other equipment that might be used in chronic care and are relevant to the measures being discussed.

- Wes Rishel divided these instruments into three groups: (1) those used in the hospital or a large clinic, (2) those used in the home by a clinician, and (3) those used in the home by the consumer without a clinician present. There are substantial differences in the workflows and the way the data are integrated back into managing care. For example, there are major vendors of communication services—cable providers and phone companies—that are looking to be able to deliver devices for home use and take responsibility for first-line support. Those are issues that do not surface when a nurse brings a device into the home. Also, he suggested organizing the panel so that the Workgroup can hear from stakeholders across this range of uses.

- Dixie Baker explained that there are significant interoperability issues around scenarios in which home devices are queried by the provider remotely.

**6. Update on the Direct Project**

ONC's Arien Malec reported on the first instances of production usage of NHIN Direct, 10 months after the start of the project. He reviewed three instances of first production usage, noting that they are starting to see a number of significant announcements in terms of interesting ways that Direct is being used in health care and public health, and hopefully soon in driving down cost through information exchange.

In December, the Privacy and Security Workgroup provided a helpful review of the project, leading to a subsequent revision that addressed concerns highlighted in the review. The final specification is in its last moments of consensus, and Malec indicated that consensus approval likely will be reached soon.

The March 29 HITSC meeting has been set as the target to announce that the Direct Project has completed its active work, and they will be ready to turn over all of their metrics and findings to the Committee. Ultimately, they want to make sure that there is a level of commonality so that everybody can reach everybody. He used his own San Francisco neighborhood as an example, explaining that there are any number or organizations within 10 miles of his house that are on completely different systems. Many transitions of care cross those networks. Having a common layer between all of these networks will help to achieve the goals of meaningful use.

*Discussion*

- Cris Ross commented that Direct is important in and of itself, but also important in terms of catalyzing people to think about things innovatively.

- Linda Fischetti expressed hope that the Committee could receive an update on Exchange at its next meeting.

- Wes Rishel commented that a key point early on in Direct was to separate the transmission of the data from the standards for how the data are packaged internally. It seems evident that this was the right thing to do. He asked, what is given up by separating those two? Malec explained that in every instance, the debate moves quickly from transport to workflow to content. There is a level of indirection that needs to happen when a package is received to determine into which part of the workflow it needs to get integrated. When physicians use EHRs, workflow is incredibly important—clumsy or inelegant solutions are not used.

- Malec explained that some of the rich packaging was deliberately sacrificed in order to have transport protocols that can be used in multiple scenarios. The upside is, the same transport can be used with multiple workflows. The downside is, the recipient has to work a little harder at figuring out what has been received. Because of the specifications being used (standard SMIME), the sender and receiver themselves make the decision in terms of where the point of encryption/decryption lies. How much or little they choose to expose to their business associates is completely up to the organization.

- Ross suggested that they extract the lessons learned from the Direct Project. He commented that it had a very effective review process. Lessons could be pulled from this to the S&I Framework project. Direct did everything that was necessary but did not try to overreach. They are seeing in the implementations that different people are going to be able to interact in different ways.

## 7. Progress Report: S&I Framework Projects

ONC's Doug Fridsma reminded the group that in December, this Committee offered feedback on a list of initiatives, and those initiatives were operationalized after that meeting. He expressed hope that the Committee will have continued engagement as it thinks about new things that need to be worked on, not only regarding standards already adopted, but also about Stages 2 and 3.

He outlined three initiatives that have been fully launched: (1) clinical document architecture (CDA) consolidation, (2) transition of care, and (3) lab interface improvement. For each project, they have a robust initiative committed membership, but they are still welcoming organizations to be committed to each of the projects.

One of the lessons learned in the Direct Project is that success is driven by the community. Involving motivated, engaged people in the initiative results in a better product. The ONC wants to support each of these efforts and stand them up, but it does not want to be the entity driving things to make them happen.

Fridsma presented a graph of registrants on the S&I Framework wiki. In January there were 50 registrants; since then, the number has grown to approximately 350 registrants. Another graph highlighted those who have committed to implementing the activities coming out of this initiative. He explained that the S&I Framework exists to support the standards development community to produce standards that drive towards cross-fertilization. It is not intended to undermine standards development organizations, but to assist in areas in for which there is more than one standard for a particular set of problems, or where there is a need for multiple standards organizations to work together.

With regard to the National Information Exchange Model (NIEM), one thing they found useful about it was the process, but not necessarily the model. There are things that need to be added in and leveraged from other existing models. They learned in the Direct Project that organizing and harmonizing against many use cases and standards is a complex and difficult process. They could have endless meetings to come to consensus, but if in fact they choose agreed-upon and targeted goals and drive towards them, they do not have to work with abstract models, which cannot be tested.

The Direct Project taught them to engage the HITSC early, and get early feedback. They are trying to figure out how to manage this internally, with their contractors. They must also coordinate with federal partners, including the National Institute of Standards and Technology (NIST).

There is much cooperative work to be done: the HITPC has asked the HITSC to address standards for certificates and directories. The draft meaningful use Stage 2 recommendations from the HITPC include many explicit and implicit asks to the HITSC. The S&I Framework provides a approach for operationalizing these requests.

Arien Malec commented that if one assumes that the ONC and CMS are going to follow more or less the same timeline for Stage 2 as was followed for Stage 1, then any of the raw materials that need to be in the update to standards certification rule must be developed and included at the beginning of October. This means that a tremendous amount of work needs to get done on a large dimension of activities. The HITSC, HITPC, contractors in the S&I Framework, the broad healthcare community, and federal partners must collaborate effectively to accomplish this.

Halamka summarized that the Quality Workgroup must be reinvigorated and work on e-measures and QDS education. The Privacy & Security Workgroup will work on provider

directories and certificates. The Clinical Operations Workgroup will examine devices and also likely patient matching. It seems as if that Clinical Operations group will also be the right place for the S&I Framework articulation on their three projects. The Implementation Workgroup will close the loop in terms of the test scripts, being sensitive to the impact on the community, and looking at barriers and accelerators.

**Committee Discussion**

- David Lansky noted that he has heard some familiar with the S&I Framework projects ask about how the six or seven contractors can work together effectively. Doug Fridsma commented that these efforts will fail if only the contractors work on them. The ONC can encourage participation, and has the ability to task contractors with certain activities. Interested parties who do not want these efforts carried out entirely by contractors are encouraged to sign up on the wiki and participate in the projects. Arien Malec added that contract performance and mission performance are aligned. Mission performance, by definition, is out of the immediate hands of the contractors.

- Cris Ross commented that appears that much of what the S&I Framework focuses on messaging and exchange. One of the shortcomings of HL7 was that it focused on exchange. He asked to what extent the HITSC will address these strategic issues and how best to represent shared modeling of information not for its exchange, but rather for its conceptualization. Abstraction can be effective, in that it can drive practical interoperability and interchange. Focusing on this after the information has been generated and moved through its sources, and trying to standardize at the interface level is an effective tactical plan. However, it is prudent that behind that interoperability and exchange goal, there be some indication of how they will come to a shared conceptualization of these elements. Where in this interoperability process is the notion of harmonizing or generating a shared information model or set of semantic relationships that can in turn inform and drive the exchange metaphors? Doug Fridsma acknowledged that there are other ONC programs looking at the issues outlined by Cris Ross, and the Office has not yet determined how best to manage them.

Stan Huff commented that the issues that arise related to producing standards are tradeoffs between quality, speed, and openness. When conflicts arise, what are the details of governance in this process? His suspicion is that when they are up against a deadline and the standard ANSI consensus process is going to be too slow, the decision-making will be taken internally into the ONC. If this happens, others will have to respond during the regulatory process, where one must prove that what is being proposed is incorrect, ineffective, or inappropriate as opposed to a more open process where all of the opportunities can be considered equally. Fridsma said that Huff has articulated the problem that they face. Strong leadership can drive part of the solution, and this Committee can help.

**8. Public Comment**

Imran Chaudhri of Apixio expressed enthusiasm for NHIN Direct and appreciation for those who have been working on its development. He commented that it is difficult to determine when

meetings are held and how to participate or listen in on conference calls. He suggested that there would be more participation in these types of activities if the information for participating was disseminated more effectively.